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ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR 10/743,667 12/22/2003 John Collier ETH-5115 7614 **EXAMINER** 27777 7590 09/11/2006 PHILIP S. JOHNSON POUS, NATALIE R JOHNSON & JOHNSON ART UNIT PAPER NUMBER ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 3731

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	on No.	Applicant(s)		
Office Action Summary		10/743,6	37	COLLIER ET AL.		
		Examine		Art Unit		
		Natalie Po	ous	3731		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
2a) ☐ 3) ☐	Responsive to communication(s) filed on <u>22 December 2003</u> . This action is FINAL . 2b) ☑ This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
 4) Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-14 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Application Papers						
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 						
Priority u	nder 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152)						
. —	Paper No(s)/Mail Date <u>12/22/03</u> . 6) Other:					

Application/Control Number: 10/743,667

Art Unit: 3731

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kletschka et al. (US 3910281).

Regarding Claim 1, Kletschka teaches a suture anchoring device comprising: a first retaining member (24e) having a first surface, a second surface and a first outer edge; where the second surface lies in a first plane; the first retaining member having an opening (19e) that extends from the first outer edge to an inner point of the first retaining member; a second retaining member (18e) having a third surface, a fourth surface and a second outer edge; where the third surface lies in a second plane, the second retaining member having a holding means (19e); a coupler (23e) having a third outer edge and a cross-sectional area taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first retaining member taken in a plane parallel to the first plane (fig. 5); where the coupler joins the first retaining member to the second retaining member at the second surface and third surface; wherein the second and third surfaces are parallel to each other and non-coterminous.

Regarding Claim 2, Kletschka teaches a suture anchoring device comprising: a first retaining member (24e) having a first surface and a second surface; where the

second surface lies in a first plane; the first retaining member having an opening (19e) that extends from the first surface to an inner point of the first retaining member; a second retaining member (18e) having a third surface and a fourth surface; where the third surface lies in a second plane; a coupler (23e) having an outer edge and a cross-sectional area taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first retaining member taken in a plane parallel to the first plane; where the coupler joins the first retaining member to the second retaining member at the second surface and third surface; wherein the second and third surfaces are parallel to each other and non-coterminous (fig. 7).

Regarding Claim 3, Kletschka teaches the suture anchoring device of claim 1, where the opening (19e) on the first retaining member extends from the first outer edge to the third outer edge of the coupler (fig. 7).

Regarding Claim 4, Kletschka teaches the suture anchoring device of claim 1, where the opening on the first retaining member extends from the second surface to the first surface (Fig. 7).

Regarding Claim 8, Kletschka teaches the suture anchoring device of claim 1, where the coupler (23e) is a cylindrical member.

Regarding Claims 10-12 Kletschka teaches the suture anchoring device of claim 1, where the cross-sectional area of the first retaining member taken in a plane parallel to the first plane is substantially the larger, smaller or the same as the cross-sectional area of the second retaining member taken in a parallel plane (fig. 7), it is noted that

Application/Control Number: 10/743,667

Art Unit: 3731

depending on where in the retaining members the cross section is taken, the cross sectional area will vary.

Regarding Claim 13, Kletschka teaches the suture anchoring device of claim 1 where surfaces and corners are rounded (fig. 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kletschka in view of Pierce (US 4823794). Kletschka teaches all limitations of preceding dependent claim 1 as previously described, but fails to teach where the second outer edge of the second retaining member further comprises a fifth surface and a sixth surface that lie nominally perpendicular to the third surface of the second retaining member, and the holding means is an opening extending from the fifth or sixth

Art Unit: 3731

surface to within the second retaining member, and where the opening further comprises an entrance and a rear surface and the width of the entrance is less than the width of the rear surface. Pierce teaches a suture anchor device wherein the retaining member (10) comprises a fifth surface and a sixth surface (32) that lie nominally perpendicular to surface (14) of the retaining member (10), and the holding means (24) is an opening extending from the fifth or sixth surface (32) to within the retaining member, and where the opening further comprises an entrance (28) and a rear surface (24) and the width of the entrance is less than the width of the rear surface (fig. 1) in order to secure the suture within the opening. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kletschka as taught by Pierce in order to further secure the suture within the opening.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kletschka in view of Wixey et al. (US 2005/0096699). Kletschka teaches all limitations of preceding dependent claim 1, but fails to teach where the holding means is a hook on the second retaining member. Wixey teaches a suture anchor wherein the holding means is a hook (370) to aid in securing the suture to the suture anchor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kletschka with a hook on the second retaining member as taught by Wixey in order to aid in securing the suture to the suture anchor.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kletschka in view of Biggs et al. (US 6599311). Kletschka teaches all limitations of preceding dependent claim 1 as previously described, but fails tot each where the coupler is a

Application/Control Number: 10/743,667

Art Unit: 3731

helical member. Biggs teaches a suture anchor wherein the device is helical in order to aid in preventing movement of the suture along the anchor (Columns 20 and 22, proximate lines 35-40 and 30-38 respectively). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connector of Kletschka with a helical structure as taught by Biggs in order to aid in preventing movement of the suture along the anchor.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kletschka in view of Lyons et al. (US 2004/0260344)

Kletschka teaches a method of securing a suture used in a surgical procedure comprising the steps of: (a) locating a suture anchoring device (10e) in the proximity of a suture site, the suture anchoring device comprising: a first retaining member (24e) having a first surface, a second surface and a first outer edge; where the second surface lies in a first plane; the first retaining member having an opening (19e) that extends from the first outer edge to at least partially through the second surface to an inner point of the first retaining member; a second retaining member (18e) having a third surface, a fourth surface and a second outer edge; where the third surface lies in a second plane, the second retaining member having a holding means (19e); a coupler (23e) having a third outer edge and a cross-sectional area taken in a plane parallel to the first plane that is smaller than the cross-sectional area of the first retaining member taken in a plane parallel to the first plane; where the coupler joins the first retaining member to the second retaining member at the second surface and third surface; wherein the second and third surfaces are parallel to each other and non-coterminous

Art Unit: 3731

(fig. 7); (c) wrapping the suture (11e) around the third outer edge of the coupler (23e); and (d) introducing the suture into the holding means (fig. 7). Kletschka fails to teach introducing the suture into said opening. Lyons teaches a suture anchor comprising an opening (36) and a holder (22), wherein the suture is introduced to both the introducer and the holder (fig. 10) in order to securely attach the suture to the anchor. It would have been an obvious to one of ordinary skill in the art at the time the invention was made to introduce the suture to the opening as well as the holder in order to aid in securing the suture to the anchor as taught by Lyons, since Kletschka has disclosed that the suture may be introduced to either the holder or the opening.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/743,667 Page 8

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP 8/24/06

> ANHTUAN T. NGUYEN SUPERVISORY PATENT EXAMINER